

# Guide for Guidelines

A guide for clinical guideline development

*The mission of the International Diabetes Federation is to work with our member associations to enhance the lives of people with diabetes.*



**Website and IDF**

A version in pdf format is posted on the IDF website ([www.idf.org](http://www.idf.org)). Information on complementary and other IDF activities is also available on this website, with contact information.

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**Duality of interest**

No issues of duality of interest appear to arise from this work or publication.

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## Foreword from the IDF Presidents

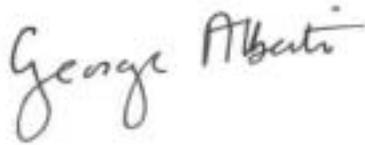
**D**iabetes is an increasing problem throughout the world and is a major contributor to the growing burden of chronic disease, especially in developing countries. It is associated with significant morbidity and decreased life expectancy due to its complications, which include heart disease, stroke, amputation, blindness and kidney failure. Diabetes reduces quality of life, especially in people with complications. It is also associated with increased psychosocial problems including depression and anxiety.

The economic burden to the individual and their family, the health system and society has been well documented in countries throughout the world. People with diabetes cost the health system more than people without diabetes, and costs are directly related to the presence or absence of complications.

There is good evidence that diabetes complications can be prevented or delayed through efforts to improve diabetes care and correct blood glucose, blood pressure and lipid abnormalities, as well as by avoiding smoking and excessive food intake, increasing physical activity and controlling body weight. The cost-effectiveness of interventions to improve diabetes care has been well established by many studies, such as the UKPDS.

Unfortunately, the practice of diabetes care is still far from uniform, both within countries and between countries. Guidelines are an essential component of achieving quality diabetes care for all people with the condition. Guideline recommendations define standards for care, and use evidence-based interventions to achieve those standards, in order to guide healthcare professionals, people affected by diabetes, policy-makers and administrators.

The *Guide for Guidelines* has been prepared to assist countries, organizations and individuals who wish to develop such guidelines. The document draws on the worldwide experience of many who have already been through this process, and emphasizes other essential aspects of guidelines including implementation and evaluation.



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# Introducing this Guide

## Who might use this Guide?

- Those involved in the care of people with diabetes
- Those about to prepare a guideline to aid delivery of that care
- Those who wish to draw on the experience of others in developing such a guideline.

## Who are we, and why have we prepared this Guide on behalf of the IDF?

We have all been involved in developing guidelines as tools for decision-making to improve diabetes care. Coming from the different IDF regions, we are united in the effort to reduce the increasing burden of diabetes worldwide. We are aware that developing guidelines has required the development of significant expertise, in addition to considerable energy and resources. We are also aware that, to date, implementation and evaluation have not received adequate attention. In preparing this Guide, we have examined and discussed the range of guidelines already developed in the field of diabetes, and the available information on development and implementation of high-quality clinical practice guidelines, both within the diabetes world and elsewhere. This Guide has been prepared for the IDF Clinical Guidelines Task Force at the request of the IDF Executive Board.

## What is in this Guide?

This Guide includes (see *Contents* for details):

- an overview of guidelines
- planning and preparation issues which need to be considered before you embark on the process of guideline development
- step-by-step advice on developing, implementing and evaluating guidelines, taking into consideration varying resource limitations in different settings around the world
- sources of further information (mostly in English) which you may find useful.

# Understanding General Guideline Issues

This section:

- deals with historical aspects of guidelines and why the current methods have been adopted
- briefly addresses issues of evidence
- discusses some of the differences between guidelines at different geographical levels of care — particularly national versus local
- explains why guidelines are themselves very cost-effective
- discusses *derived guidelines* and how they simplify guideline development.

## 1.1 Historical overview — international diabetes guidelines

Any textbook will contain examples of short, stepped protocols for investigating a medical condition, or for managing it. Most such protocols were intended as guidance rather than rigid structures. The term ‘guidance’ merely refers to more limited advice than a ‘guideline’, the latter encompassing all aspects of an area of healthcare. It is guidance to advise the use of digital cameras in surveillance for eye damage; a guideline would include other aspects such as recall systems, use of eye drops, etc.

A textbook management guideline is often the effort of one author, and does not give reasons for the proposed advice, which is usually derived from a reading of the literature combined with the influence of clinical experience. Clinical experience itself is of diverse input in terms of both breadth (numbers of cases) and depth (diversity of cases), with a significant input from chance, and interpretation coloured by the peculiarities of human beliefs and thinking. Accordingly, this kind of guideline is often biased by the views and interests of a few experts.

The evidence-based guideline movement has grown from a desire to address this potential for bias, and thus provide clinical practice recommendations based on a critical and unbiased review of available evidence.

In Europe, at about the time of the St Vincent Declaration in 1989, the movement to raise the profile and quality of diabetes care led to the first multinational guideline. Notable here was the use of a group of experts from different healthcare cultures in an attempt to use consensus working to reduce the bias of individual opinion. Furthermore, the output was put to a large meeting for approval. As a consultation exercise this was perhaps too grand to be effective in gathering other opinions, although it did provide a useful early example of recognizing the value of spending money on an implementation/dissemination activity.

### **Evolution of diabetes guideline development process**

- **Opinion:** individual ➔ group ➔ multidisciplinary ➔ formal consensus
- **Evidence review:** expertise ➔ shared expertise ➔ literature overview ➔ systematic
- **Consultation:** individual ➔ group feedback ➔ limited consultation ➔ open, formal consultation
- **Funding:** industry ➔ multi-industry ➔ stakeholder/government/organization ➔ government sourced, editorially independent
- **Publication:** textbook ➔ local protocol ➔ consensus guideline ➔ evidence-based guideline



Nevertheless, this 1989 European guideline was narrowly led, and the influence of that on its content could be felt. Furthermore, the funding was from the pharmaceutical industry and, although this was acknowledged and transparent, concerns of inappropriate bias inevitably arose in the minds of some readers.

In the European guideline initiatives of 1993, a broad-based development group was assembled to dilute individual belief even further, also reducing any perceived possibility of lobbying from interested parties. This initiative included non-medical multidisciplinary team members and people with diabetes. Nevertheless, this development group made no formal attempt to review the evidence underlying diabetes care, instead relying on the depth of knowledge of the literature of 33 experts with diverse interests in diabetes care.

The 1998 update of this activity made some attempt to deal further with two of the remaining problems, firstly by diluting perceptions of lack of independence from individual players in the pharmaceutical/diagnostics industry, and secondly by a somewhat more formal approach to evidence review. The first of these required multi-company funding. To address the second point, pairs of experts were asked individually to review a limited part of the literature and to report back to the full group, both for discussion of their interpretation and as a check on the completeness of that review. It is interesting that the output corresponds closely to the evidence-based guidelines that are now being produced, and without significant contradiction.

Meanwhile, concerns about bias were leading to the development of the concept of so-called ‘evidence-based’ guidelines, based on a systematic search of the literature and a formal review of the quality and type of evidence. Diabetes guidelines anchored in such a process have now appeared (or are appearing) in a number of countries, funded by governments and/or patient/professional associations. It is this trend, which has made the guideline development process more remote from the interested professional, that has partly prompted this *Guide for Guidelines*.

## 1.2 What is evidence?

Modern guideline development has focused on supporting clinical practice recommendations with evidence. In the medical guidelines world it is important to keep in mind the meaning of the word ‘evidence’.

In normal English, ‘evidence’ means any information that should have a valid influence on an area of thinking. Evidence has two properties, the first being the extent of its relevance to that area of thinking, and the second its degree of reliability or truth. Strong evidence will be sound in both properties, but if there is marked weakness in either property then the evidence should have little influence on an area of thought.

Scientific reasoning has long attempted to be more sophisticated and attach probabilities to hypotheses. In the scientific world, new evidence has the effect of shifting the probability of something being true, the extent of the shift depending on the validity and relevance of the new evidence, when compared to the strength of other evidence underpinning the hypothesis. Broadly this thinking is due to Bayes and his followers over the last 300 years.

The development of the concept of the null hypothesis, and of the p-value as the outcome of a hypothesis-testing study, presented a challenge to the Bayesian school. However, this approach did remove some of the problems of bias and judgement which can affect the probability assignments of the Bayesian approach. Essentially, the null hypothesis assumes there is no prior knowledge, while the p-value as it is usually used is taken as a categorical ‘true’ or ‘not true’ as to whether the hypothesis is rejected.

### *Evidence grading*

Recognizing that not all evidence is of equivalent quality, systems have been developed to grade the level of evidence to take into account a number of features of a study. These include the study type and quality, and the relevance of the study findings, both clinically and to the target population. Evidence grading has proved valuable in guideline development.

However, there are now a variety of systems of grading of evidence. While these are useful in categorizing studies, it is important to recognize their limitations. For example, many focus on the type of study without giving due consideration to the study quality. All systems assign a high evidence level to a randomized controlled trial (RCT), but this should not be taken to suggest that this is the only kind of evidence admissible

in making clinical judgements. Indeed, RCTs are of variable quality and may not be applicable to the clinical problem (that is, they may have a limited probability of being appropriate to the individual in front of the doctor). In these circumstances, relevant non-RCT evidence should be taken into account.

As an example, a poor meta-analysis will generally be given a high grade of evidence while the opinion that insulin is a necessary treatment in Type 1 diabetes will be given a low grading because it has not been subjected to an RCT, which would obviously be unethical. Clearly, then, the strength of the clinical recommendations must go beyond the so-called level of evidence. Accordingly, a guidelines *Development Group* (see *Section 2*) will find itself exercising considerable judgement in formulating clinical recommendations, which is why this group needs to be broadly based with high levels of expertise from different disciplines of diabetes care.

Lastly, RCT evidence is absent for many areas of diabetes care. An important part of the gap is filled by studies in people who do not have diabetes, studies in people who have a different type of diabetes, epidemiological analyses (including those of RCT populations) and cohort studies.

The lack of RCT evidence is not filled by 'expert opinion'. It is filled by informed consideration of the value and validity of studies from people who do not have diabetes, studies in people with a different type of diabetes, epidemiological studies, cohort studies, and pathogenetic knowledge from clinical and laboratory investigations, usually reviewed together. Such a broad analysis can result in a strongly based clinical practice recommendation.

'Once the evidence has been compiled ... the development group need to decide what recommendations can be made ... This is perhaps the most difficult part of the whole process, and requires the exercise of judgement based on experience as well as knowledge of the evidence and methods needed to generate it.'

*Considered judgement, SIGN*



### 1.3 National and local guidelines

It might be assumed that all quality guidelines producing recommendations for diabetes care would appear similar in style as well as content. In practice this is not the case, style depending partly on whether the intention is to provide immediate advice to the healthcare provider (a 'desktop guide' or 'clinical practice recommendations') or a higher level of advice on care processes.

The latter can be thought of as providing a template on which the local practice recommendations are based, and is often the form followed by national and international guidelines. For example, national guidelines may specify that eye screening should be performed annually, but the details as to the systems and personnel used, the recall system, and involvement of specialist ophthalmologists may have to be decided locally, and be the subject of a locally adapted guideline. Indeed, even where the technology (such as a digital camera) and referral guidelines are specified, details of who takes the photographs, who screens the photographs for abnormalities, and quality control, are likely to be matters for local protocols.

To some extent this will be a consequence of the depth of clinical questions (see *Section 2*) addressed by the evidence review. A broad question on the use of oral glucose-lowering medications in Type 2 diabetes is not likely to produce detailed recommendations on the use of specific sulfonylureas at specific dose levels and visit intervals at particular points in the natural history of the condition, or the alternatives to be used in the case of specific kinds of side effects, or what to do in people with other concurrent conditions or using other therapies. These issues might, however, be addressed in a guideline limited to therapeutic issues.

## 1.4 The cost-effectiveness of guideline development

It is usual in many areas of activity to spend a significant proportion of one's budget on improving processes and quality monitoring. In industry this might approach 10% of turnover. With few exceptions, it is rare to find more than a small part of 1% of healthcare expenditure devoted to such activities, including guideline development.

Expenditure on a diabetes guideline has the potential to be one of the most cost-effective forms of healthcare expenditure, provided the result is properly implemented. In a population of 1 000 000 people with diabetes (a country of 50 million people with moderately low prevalence), perhaps 35 000 will die of a diabetes-related event each year. On this basis a US\$300 000 guideline which results in just a 10% implementation of multi-risk-factor-reduction strategies may do so at a cost of around US\$100 per life-year saved, before considering reductions in morbidity. However, since a guideline only has this real value after it is implemented, it is imperative that development of a guideline includes an implementation strategy.

*Expenditure on a diabetes guideline has the potential to be one of the most cost-effective forms of healthcare expenditure, provided the result is properly implemented.*

## 1.5 Basic approaches to guideline development

There are two basic approaches to developing an evidence-based guideline:

- *Full-process guideline*
- *Derived guideline.*

A *full-process guideline* involves a full and systematic development of the clinical questions to be addressed, and develops recommendations supported by complete and formal evidence searching and review, using primary sources.

A *derived guideline* similarly develops clinical questions, but then seeks out and adapts previously developed *full-process guidelines*, updating the evidence base and seeking supporting evidence to develop recommendations for local circumstances.

The extent to which the project will be based on new work or on work done by others will determine the complexity of the task. Preparing a *derived guideline* can be a relatively simple process. On the other hand, preparing a *full-process guideline* will require a more complex management structure and considerable resources and time.

The process to be followed will need to be agreed at an early stage, since the steps to be followed in guideline development will be partly determined by the approach adopted.

# Developing Guidelines

This section provides step-by-step advice on the process of guideline development, and is divided as follows:

- Section 2.1: planning and preparation
- Section 2.2: developing the recommendations
- Section 2.3: practice points.

Each subsection begins with its own checklist.

## 2.1 Guideline development — planning and preparation

### Guideline development checklist 1

#### Planning and preparation

1. Consider the guideline remit
2. Identify stakeholder organizations and their representatives
3. Consider including other expertise
4. Establish a management structure
5. Identify and involve endorsing organizations
6. Announce initiative and register interested parties
7. Determine the scope (see *Scoping checklist*, page 14)
8. Identify timescale and plan guideline development process
9. Consider guideline implementation process and barriers
10. Consider budget and obtain funding
11. Appoint staff to support development
12. Agree *Development Group* membership

For *Developing the recommendations*, see *Guideline development checklist 2*, Section 2.2



### 2.1.1 Consider the guideline remit

Your target population will be people with diabetes unless your guideline is intended to include measures to prevent diabetes. In some situations, other people affected by diabetes (parents, carers) will need to be included.

In general, you will be targeting a geographical population with diabetes (national, regional or local), rather than a population under the care of a particular service or type of service, but this will not always be the case.

Many guidelines cover all the main areas of diabetes care (see *Scoping checklist*, page 14), but some guidelines are restricted to one target area, such as foot care, or blood pressure lowering, or diabetes and pregnancy.

If resources allow, it is better to prepare guidelines for Type 1 and Type 2 diabetes separately, and certainly to approach children with diabetes separately from adults (the professionals and carers are usually a different group of people from those involved with adults).

#### Checklist on remit

- What geographical population?
- What sites of care?
- What areas of diabetes care?
- What types of diabetes?
- What target audience?



You need to have a clear perspective on what aspect of diabetes care, covering what population, the prospective guideline is to be developed for. Otherwise, you will be unable to define who should contribute to the activity and what resources will be necessary to develop the guideline.



The target audience for the guidelines may include healthcare professionals (medical and non-medical, primary care physicians, and specialists), administrators and policy-makers, and people with diabetes. The final format and language of the guideline may need to be adapted for different target audiences.

### 2.1.2 Identify stakeholder organizations and their representatives

Involvement of people with diabetes in any guideline development is a must, as is involvement of their representative organization (national or local).

People with diabetes give unique and valuable perspectives on the interpretation of evidence and the formulation of recommendations. Diabetes associations can be powerful in guideline implementation.

Professional groups (diabetes educators/nurse specialists, nutritionists, family practitioners, physicians) have different skill mixes. Ensuring that their national or local organizations supply representatives to your guidelines initiative provides both needed expertise and ownership.

The overlap of diabetes into most other areas of medical practice means that a wide variety of other stakeholder organizations could be involved. Examples might be anaesthetists, if diabetes surgical care is to be included, or alternative medicine practitioners where these are central to healthcare provision. Involvement of all such organizations, often at *Steering Group* (see below) level, but certainly in the consultation process, can have a marked impact on guideline acceptance and implementation.

### 2.1.3 Consider including other expertise

There may be individuals outside the representative organizations whose talents, energy, or role as opinion leaders will help the guideline development process and in particular the more difficult area of implementation. Securing their engagement in the guideline initiative is best done at the earliest planning stage.

### 2.1.4 Establish a management structure

The management structure underpinning guideline development can take a variety of forms. Regardless of the scope of the guideline development project, the management structure would usually include the following two levels:

- *Steering Group*
- *Development Group*.

However, with smaller projects that primarily involve adapting guidelines prepared by others, only one committee may be necessary.

The *Steering Group*, meeting infrequently, is a useful means of ensuring that the representatives of all stakeholder organizations (see above) can be heard. It also provides the means of reviewing management performance and the draft recommendations. Ultimately, this group will sign-off the guideline, giving it broad legitimacy.

The *Development Group* has the responsibility for considering the evidence identified by systematic review, and for formulating the clinical recommendations.

Additionally, an important consideration is the *management* of the project, and this will often require dedicated personnel. The above groups will usually need to be supported by people with expertise in literature and evidence review — *a technical team*.

#### Stakeholder organizations: examples

- Patient associations
- Professional organizations (medical)
 

Family doctors	Physicians
Vascular surgeons	Cardiologists
Ophthalmologists	Nephrologists
- Professional organizations (others)
 

Nutrition	Podiatry
Psychology	Nursing
Healthcare management	
- Government
- Public health
- Insurance companies
- Alternative medicine



#### A possible management structure

##### *Steering Group*

Representatives of all major stakeholder organizations

##### *Development Group*

People with diabetes, multidisciplinary professionals, project management and technical staff



### 2.1.5 Identify and involve endorsing organizations

Endorsement from an international organization (IDF/WHO) or national organization (patient association/professional association/government) can be a powerful means of gaining acceptance of a new guideline. Most such organizations have strict rules on collaboration. Engagement at the outset of guideline development, and an understanding of their rules, will help in obtaining subsequent endorsement.

### 2.1.6 Announce initiative and register interested parties

Announcing the project will officially begin the process, and may identify other individuals or organizations who can contribute to the project. It may also identify other initiatives in related fields, perhaps saving duplication of effort, and offers of help may come from other countries with similar ideas. Parties that express an interest should be documented and kept informed of progress throughout the guideline development. People from the media and marketing may also be engaged in the process at this time. Such an announcement may also help motivate the teams working on the project.

### 2.1.7 Determine the scope (see *Scoping checklist*, page 14)

Scoping involves considering in detail the areas of clinical practice that will be addressed by the guideline. This has to be agreed with other stakeholders.

This is particularly important for those areas that overlap with other speciality areas. Examples include diabetes prevention (public health), diabetes and pregnancy (obstetrics), and tertiary care management of complications (ophthalmology, renal medicine, cardiology, vascular surgery, stroke medicine). This also has consequences for the logic of a diabetes guideline — retinal screening assumes that detecting retinopathy is useful, and essentially that ophthalmologists can offer treatment for sight-threatening retinopathy with laser photocoagulation. If such facilities are not available then a decision must be made: *either* one does not have a guideline for retinal screening until such facilities are available, *or* one does have a guideline knowing that its implementation will not be possible until these facilities become available but that the guideline may help the process of acquiring the necessary facilities.

*Most diabetes guidelines take a patient-centred view, namely, that the care to be delivered is independent of the site of care.*

A special case here is the relationship between primary and secondary care for people with diabetes. Most diabetes guidelines take a patient-centred view, namely, that the care to be delivered is independent of the site of care. The relationship between primary and secondary care is not then defined, the assumption being that the assistance of secondary care is sought where management targets are not met, or when the primary care team reaches the limit of its expertise. There may, however, be circumstances in which it is desirable for the referral criteria and pathways between these sectors to be defined.

Only when the scope is well defined will it be possible to assess the workload and timescale of the guideline development process, and thus define the necessary budget.

### 2.1.8 Identify timescale and plan guideline development process

Every guideline requires time:

- to gather, review, and consider the evidence
- to formulate recommendations
- to consult with stakeholders, review responses, and collate and integrate comments
- for review by potential endorsing organizations
- for design and publication.

The precise structure of this process will depend on the breadth of coverage, and also on whether a *full-process guideline* or a *derived guideline* is being prepared. In both cases careful planning is required, taking into account the extent of the management structure and whether extra staff are to be employed for the project. Gantt chart timetabling is recommended.

**Scoping checklist** (to help in scoping the proposed guideline)*Care populations*

- National, regional, or local district
- Urban, rural
- Site of care independent (all people), or primary or secondary sectors
- Children, adults, specified age ranges

*Types of diabetes*

- Type 1 diabetes
- Type 2 diabetes
- Pancreatic or endocrine secondary diabetes

*Prevention and case finding*

- Prevention programmes
- Screening/surveillance for diabetes
- Early diagnosis

*Care activities for people with diabetes*

- Education
- Self-monitoring
- Nutrition
- Lifestyle advice, including smoking
- Psychological issues
- Clinical monitoring and assessment levels (targets)
- Oral glucose-lowering therapies
- Insulin therapy
- Hypoglycaemia
- Blood pressure lowering therapy
- Lipid-lowering therapy
- Diabetes eye damage — detection and management
- Diabetes kidney damage — detection and management
- Diabetes nerve damage — detection and management
- The diabetic foot — surveillance and management
- Ketoacidosis
- Diabetes and pregnancy — including gestational diabetes
- In-patient management — surgical and other procedures

*Special issues (additional to above)*

- Cultural and ethnic
- The newly diagnosed
- Parents and carers
- The visually, physically and mentally infirm

**2.1.9 Consider guideline implementation process and barriers**

Guideline development is rarely indicated unless there are plans, developed at the same time, for implementation of the recommendations. Two obvious exceptions are:

- International guidelines designed to inform and be sources for national and local efforts
- National guidelines where there is a political promise of some support to be forthcoming when the guideline identifies the need, or where the national guideline is intended as a lobbying tool to secure those resources.

At this planning stage, resources are needed for the process of gaining acceptance and knowledge of the guideline, rather than for changes of care that might occur as a result of the guideline. The processes of stakeholder identification and scoping consultation (above) will have involved the interested parties.

Now is the time to bring them into discussions on goals, roll-out meetings, development of supporting materials, publication on local websites, establishment of local implementation groups, and the resources and budget needed for these activities.

### 2.1.10 Consider budget and obtain funding

Funding may already have been allocated depending on who initiated the project. The budget will be determined by the scope of the project, and needs to cover staff time, infrastructure, communication, and travel costs of guideline development. Experience of guideline development suggests that it is an unpredictable activity, which often takes longer than expected. Contingency funding is therefore advisable.

Similarly, a budget should be set and funding obtained for the processes of publication and for planning implementation of the guideline.

#### Major costs

- Management/evidence review staff
- Clinical advisor
- Travel costs of group meetings
- Communication costs
- Publishing/printing/website
- Implementation meetings
- Contingencies



### 2.1.11 Appoint staff to support development

Minimal requirements will be for administrative staff to manage communications with stakeholder and funding organizations, to co-ordinate meetings of the guideline groups, to prepare materials for those meetings and eventually for publication, and to manage the budget. Sometimes governmental, professional or patient organizations will be prepared to provide staff for these tasks. If so, it is important to be realistic about the amount of time and expertise involved.

Skilled staff are required for systematic literature searches, evidence reviews, and writing and reporting. These staff are usefully supported by a manager, and they all work with a part-time clinical advisor who has a broad knowledge of diabetes care.

Development of a *full-process guideline* may take as long as 24 months. However, a number of such diabetes guideline development initiatives have been conducted worldwide (see Table, Section 2.2.2). It is not recommended that these approaches be duplicated elsewhere, except where issues of ownership mean that this is considered necessary.

*‘... a number of such diabetes guideline development initiatives have been conducted worldwide (see Table, Section 2.2.2). It is not recommended that these approaches be duplicated elsewhere, except where issues of ownership mean that this is considered necessary.’*

### 2.1.12 Agree Development Group membership

The *Development Group* has the responsibility for considering the evidence identified by systematic review and for formulating the clinical recommendations.

In some ways these are the jury of the development process, as they have the responsibility for translating evidence into focused and specific recommendations (see Section 1.2).

Accordingly, the *Development Group* should be selected with care, and should include stakeholders directly relevant to the scope of the guideline. Desirable qualities include a broad view of the subject, and the ability to listen and analyse the views of others, and to help pull together an agreed judgement on the meaning of the available evidence.

Diabetes care is classically multidisciplinary, and is delivered in the primary, secondary and tertiary care sectors. The *Development Group* should be multidisciplinary and include representatives from each of these sectors, depending on the guideline topic. Consideration of prevention of diabetes, or screening for diabetes, will usually benefit from input from the public health/epidemiology sectors.

Reference has been made above to the particular skills of people with diabetes who are able to generalize their

#### Development Group — possible members

- People with diabetes
- Diabetes educator/nurse specialist
- Nutritionist
- Physicians with diabetes expertise
- Family doctors
- Primary healthcare nurse
- Public health professional/health economics expertise/health funders
- Tertiary care specialists when required
- Podiatrist



experience beyond its impact on themselves. The IDF strongly recommends that people with diabetes possessing such qualities be part of any *Development Group*.

*Development Group* members must be able to work well in the group environment and be able to take decisions. It may be difficult to find people with diabetes who are not healthcare professionals and yet possess the confidence to contribute to this process. Where possible, people should receive training in the skills needed.

## 2.2 Guideline development — developing the recommendations

### Guideline development checklist 2

#### Developing the recommendations

1. Develop the clinical questions
2. Search for other recent guidelines addressing the questions
3. Search for recent evidence reviews/meta-analyses/major RCTs
4. Review quality and relevance of evidence
5. Develop an economic perspective
6. Develop evidence statements and draft recommendations
7. Reconvene *Steering Group* for formal review and adoption of draft guideline
8. Circulate draft recommendations and evidence statements for comments
9. Obtain endorsement
10. Design output document(s) and web pages, and publish

For *Practice points*, see *Guideline development checklist 3, Section 2.3*



### 2.2.1 Develop the clinical questions

A guideline includes a set of recommendations for clinical care. To be useful, these recommendations have to be closely tied to the detail of healthcare. Ideally, these arise from decision points whose questions are tested by available evidence.

A search for the evidence addressing issues defined by the scope of the guideline depends on formulating the questions carefully. The best approach is to imagine that the person with diabetes is sitting in front of you, and ask what decisions (in the absence of prior knowledge) need to be taken about their care within each topic of care.

A useful general approach is to consider:

- Why is this a problem?
- What do I measure?
- When and how often do I measure?
- Who should do these tests and where?
- When do I intervene?
- With what do I intervene (education, first-line and second-line treatment, referral)?
- How do I know the intervention is successful?
- Does allowance have to be made for any special groups?

This approach works both for screening (and surveillance) and for therapeutic interventions.

The question may also vary with the geographical breadth of the guideline. For example, a national question might be whether and how often to screen for abnormal albumin excretion in people with Type 2 diabetes, but at the local implementation level the choice of laboratory or point-of-care test, and the recall system needed to ensure the test is done, are answers to more specific questions.

#### Full-process guideline development

Readers interested in the fundamentals of guideline development are directed to materials referenced in some of the websites listed in the Table, *Section 2.2.2*. See also [www.agreecollaboration.org](http://www.agreecollaboration.org)

#### Derived guideline development

An example of this from New Zealand, and a description of the methodology involved, can be found at [www.nzgg.org.nz](http://www.nzgg.org.nz)



Developing the questions to be answered is the first task for the *Development Group*, although the *Steering Group* will need to ensure that the questions address the scope (see Section 2.1.7) of the proposed guideline.

### Examples of guideline questions

- Is screening for diabetic eye disease worthwhile in Type 1 diabetes?
- Which screening tests should be used for detecting diabetic eye disease?
- What is the optimum site and recall system for diabetes eye screening?
- How often should people with Type 1 diabetes be screened for diabetic eye disease?
- When should a person with Type 1 diabetes be referred to an ophthalmologist for consideration of laser therapy?
- What is the target population among adults with Type 2 diabetes for blood glucose self-monitoring?
- What method of self-monitoring should be employed?
- What frequency and regimen of self-monitoring should be adopted?
- What educational support should be given to optimize self-monitoring?
- What advice should be given for interpreting/acting on the results of self-monitoring?



### 2.2.2 Search for other recent guidelines addressing the questions

The IDF does not recommend ‘reinventing the wheel’, but does strongly encourage the redesign of the wheel to suit local circumstances. A number of organizations have devoted considerable effort and spent large sums of money to develop *full-process guidelines* using personnel skilled in literature search and systematic review, people and resources not available in many countries.

Accordingly, it is strongly recommended that most new guideline developments will be *derived guidelines*, using the work performed and published by others as ‘seed’ or ‘source’ guidelines. The sources on which *derived guidelines* are based should always be stated explicitly, and copyright permission should be obtained for quotation of any published material.

**Table: Useful sources of full-process guidelines for diabetes care**

National Health and Medical Research Council	Australia	<a href="http://www.nhmrc.gov.au">www.nhmrc.gov.au</a>
Canadian Diabetes Association	Canada	<a href="http://www.diabetes.ca">www.diabetes.ca</a>
National Institute for Clinical Excellence	England and Wales	<a href="http://www.nice.org.uk">www.nice.org.uk</a>
Deutsche Diabetes Gesellschaft	Germany	<a href="http://www.deutsche-diabetes-gesellschaft.de">www.deutsche-diabetes-gesellschaft.de</a>
Scottish Intercollegiate Guidelines Network	Scotland	<a href="http://www.sign.ac.uk">www.sign.ac.uk</a>
Institute for Clinical Systems Improvement	USA	<a href="http://www.icsi.org">www.icsi.org</a>

A list of known *full-process guidelines* in diabetes is given in the table above. It may be that only the evidence statements and recommendations are available on the websites, but addresses and contact details are also given, together with references to the detailed systematic review (sometimes called a ‘health technology assessment’).

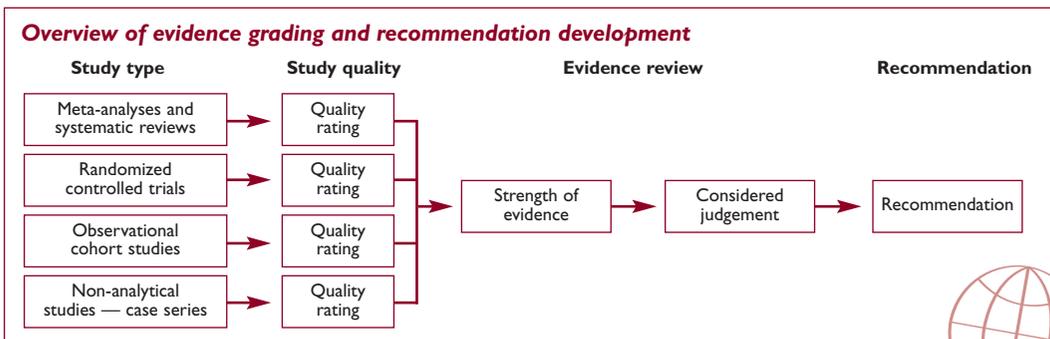
### 2.2.3 Search for recent evidence reviews/meta-analyses/major RCTs

It is not recommended that developers of *derived guidelines* repeat detailed literature searches, but they should extend the searches to include the period since the source guideline was developed. The search should specifically target local research and recent major RCTs and meta-analyses. If such studies are found, then their quality will need to be formally assessed according to criteria agreed by the *Development Group*.

Beware of assuming that one recent RCT has precedence over all former RCTs. One study is an addition to a body of knowledge, not a replacement for it. Nevertheless, in recent years diabetes care has seen a series of studies that have resulted in major changes in emphasis through confirmation of previously held beliefs. Examples are the HPS and studies with angiotensin receptor blockers.

### 2.2.4 Review quality and relevance of evidence

A guideline of quality, such as those from the organizations listed in the Table in Section 2.2.2, will include in all but its summary document the details of its development, which allows its quality to be judged. The Agree Collaboration, the New Zealand Guidelines Group and others additionally publish stand-alone documents that advise on the assessment of the quality of guidelines. A similar tool is available on a US national site ([www.guideline.gov](http://www.guideline.gov)).



New evidence should be formally assessed and graded using a quality template. Although there are many templates (again, see those used by organizations listed in the Table, Section 2.2.2), they adopt a similar approach to the study grading used in determining the strength of the evidence, which will ultimately be employed to make the guideline recommendations (see box above).

There are a number of considerations that should be taken into account in grading evidence. Because the type of study is easy to classify and thus least open to bias, it is often given particular and sometimes undue prominence in evidence grading. However, it is equally important to consider the other dimensions of evidence grading. Determining the quality of the study should include a formal assessment of its design and potential for bias (concealed randomization, matching of control population, power calculation). Unfortunately, some aspects are not so easily assessed, common examples being meta-analyses which combine studies on different populations, and RCTs on heterogeneous populations or populations not immediately applicable to the population of the new guideline.

A particular problem in diabetes care is how to consider studies (especially in the cardiovascular prevention area) done in non-diabetic people, or done predominantly in people with a different type of diabetes from the target group. The *Development Group* may well struggle to make judgements in these situations.

#### Grading the evidence — key considerations

- **Study type:** meta-analysis, systematic review, RCT, non-RCT, cohort, case series
- **Study quality:** well designed, low bias
- **Magnitude of study findings:** are they clinically significant?
- **Relevance and applicability of study:** to your clinical setting

### 2.2.5 Develop an economic perspective

Guideline implementation usually has a cost impact. However, guideline recommendations are developed to improve health outcomes and quality of life, to reduce the societal and individual economic burden of diabetes, and to optimize the use of available resources. The cost incurred should be appropriate, in the geographical context of the guideline being developed, to the degree of health gain that is evidenced from the studies. Therefore, developing a local economic perspective should be considered a normal part of guideline development (see box, *An economic perspective*, page 20).

This is not an easy task because the necessary information may not be available from the studies and any related economic analyses, and devising methods to compare economic evaluations between countries is not simple. It is suggested that relating the cost consequences of a guideline to the annual GDP per person may assist in translating an economic evaluation of a diabetes care activity from one country to another country. For example, if statins give a cost per QALY (see box below, *Understanding economic input — the jargon*) of US\$7500 in Western Europe, then that cost is about one-quarter of the annual GDP per person (US\$30 000). If the same costs per QALY were applied to a country with an annual GDP of US\$5000–10 000 per person, funding of statins through a national insurance or taxation system would be either not, or only marginally, cost-effective. However, many healthcare costs, notably salaries, will change partly in proportion to GDP, making treatment coverage more feasible. Furthermore, opportunities for skill substitution (such as trained village healthcare workers) can mean that costs of advice and screening can remain in proportion to GDP. Generic therapies, including oral glucose-lowering, blood lipid and blood pressure lowering drugs, are usually just as effective as full-price equivalents. With national contract purchasing and appropriate distribution (for example, using diabetes associations), even the costs of supplying insulin and self-monitoring reagent strips can be constrained.

Some technologies will, however, be unaffordable for the majority in poorer countries, and some proprietary drug therapies are an example. It is important to recognize that use of funds in an expensive part of the healthcare system diverts funds from more effective healthcare elsewhere, worsening the overall health of the population.

Broadly, therefore, you might apply the following economic perspective in developing the guideline recommendations:

- How does the annual GDP per person in your population relate to that of the population being used for comparison?
- What are the comparative costs of diabetes technologies and personnel between the two populations?
- How can the costs of diabetes technologies or costs of provision of care be reduced to improve cost-effectiveness?
- What are the minimum standards of care/prevention required for the target population?
- Given the economic comparison related to all these factors, what technologies might have to be reconsidered or abandoned for the time being?

### **Understanding economic input — the jargon**

**Cost-consequence analysis:** a generic term covering all forms of estimation of costs on the one hand and the related outcomes (changes in healthcare costs, measures of health, quality of life) on the other

**Cost-benefit analysis:** considers only money costs; if you spend money on ACE inhibitors to prevent diabetic nephropathy, how much money do you save on renal failure management?

**Cost-effectiveness analysis:** chooses a single type of health benefit (often life-years saved, but could be heart attacks prevented), and calculates cost per event saved

**Cost-utility analysis:** allows comparisons between different types of health outcomes by calculating the ratio of the cost of an intervention to the overall quality of life change from an intervention; 'utility' (quality of life) is expressed on a scale of 0.0 (dead) to 1.0 (full health) experienced over 1 year — this is the Quality Adjusted Life Year (QALY)

*Note: 'cost-effectiveness' is often used loosely and non-quantitatively for what would be cost-utility if formally calculated*

**Cost-impact** is not related to cost-effectiveness. It is simply the budget impact (total cost per year) of introducing a change in healthcare. An expensive technology used in very few people will often be of high cost-utility but low cost-impact, whereas a cheap technology (such as hearing aids) needed by many people will be of low cost-utility but high cost-impact



## An economic perspective

### Background

Very few guideline developers have access to the quality of economic advice that might be desired. This is unfortunate as most preventative diabetes care is not only highly cost-effective compared to, for example, treatment of AIDS or renal failure, but also has a high cost-impact due to the prevalence of diabetes.

Accordingly, the case for implementing guideline recommendations can be strongly supported by including some cost-consequence analyses.

Even the major quality diabetes guidelines (Table, Section 2.2.2) contain little economic information.

Some information is available from economic analyses of major studies (DCCT, UKPDS, HPS) and some from assessments of individual diabetes technologies (see, for example, [www.nice.org.uk](http://www.nice.org.uk) for insulin glargine, PPAR- $\gamma$  agonists, patient education, pumps).

The diabetes guidelines mentioned above all come from developed economies where the GDP per person is around US\$20 000. Any country that has a similar level of prosperity can be loosely assumed to have a similar healthcare economic perspective for the purposes of guideline development. Indeed, this applies to some populations with adequate healthcare insurance in less well-resourced countries.

### Personnel and therapy costs

In less well-off countries the costs of medical care are invariably lower than in the developed world, mainly because healthcare salaries are lower. Accordingly, guidelines for some healthcare activities (screening, education) will not need to change significantly with economic perspective, provided the recommendation is activity orientated rather than healthcare profession orientated ('feet should be assessed annually by a trained professional' rather than 'feet should be assessed annually by a state-registered podiatrist').

For many therapies, generic products are available that are so cheap as to be cost-effective in most countries. For example, the UKPDS found that generic antihypertensive drugs were cost-effective at a level below one-thirtieth (1/30) of the kind of cost-effectiveness thresholds used for new technology adoption in the UK (US\$30 000). Crudely, this suggests that, using a generic substitution policy, such therapies would remain cost-effective even in countries with an annual GDP per person of US\$1000 or less, assuming that drug costs and the cost consequences of the disease remain the same.

More difficult are non-generic therapies and insulin. Some useful guidance can be derived if calculations are already available for developed economies. If, for example, statins give a cost per QALY (see box, *Understanding economic input — the jargon*, page 19) of US\$7500 in Western Europe, then that cost is about one-quarter of the annual GDP per person (US\$30 000). If the same costs per QALY were applied to a country with an annual GDP of US\$5000–10 000 per person, funding of statins through a national insurance or taxation system would be either not, or only marginally, cost-effective.

Insulin for Type 1 diabetes is required for life. If supplies can be obtained regularly for just US\$120 per year for a child, it might appear that it should be cost-effective except in very poor communities. By contrast, supply of insulin for people with Type 2 diabetes requires a much higher level of economic prosperity (because the benefit is smaller), a difficulty that is exacerbated by the cost of self-monitoring.

For complications screening, different perspectives may apply. Screening for eye disease assumes that expensive tertiary care management is available; if it is not, then such screening does not make sense (but it may then be appropriate to recommend the establishment of such services). Screening for peripheral vascular disease may similarly seem pointless if vascular investigations/surgery are not available, but the evidence may show that foot care education can be effective and cheap in preventing amputations, and so it would still be recommended. Occasionally, the economic/resource perspective will cause paradoxical jumps in advice — where laboratory screening for microalbuminuria becomes relatively expensive or unavailable, it might make sense to treat all people with Type 1 diabetes with generic ACE inhibitors from 10 years after diagnosis to prevent diabetic nephropathy.



### **Relating economic perspectives of available evidence-based guidelines**

The economic perspective of the countries in which current quality diabetes guidelines are found is a GDP per person of around US\$20 000 per year. At present many of these countries use a figure of around US\$30 000 for the approximate cost per QALY threshold below which fully evidenced health technologies should be implemented. Less well-evidenced interventions would need to be much more cost-effective to be funded — a cost per QALY of US\$15 000 or US\$7500 might be demanded.

*For comparison with your country:*

- If costs of interventions are similar, some crude feel for the local applicability of cost-effectiveness can be gained by relating cost per QALY to your local GDP.
- Local GDP can also be used to modify the above cost per QALY thresholds for determining when an intervention should be considered for implementation.
- However, be aware of local variations in costs, which may increase or decrease the cost per QALY considerably.



### **2.2.6 Develop evidence statements and draft recommendations**

For each question it is the function of the *Development Group* to review the quality of the evidence and use this review to formulate draft recommendations. The systematic derivation of evidence statements, and the sources of evidence used in formulating them, should be documented. Disagreement on the quality or applicability of a study will need to be resolved, and again this should be documented.

Developing recommendations from the available evidence is perhaps the most difficult, judgemental and interesting part of the guideline process. The *Development Group* needs to ensure that it specifically addresses the guideline question, considers the opinions of all members, and formulates precise and unambiguous statements in well-structured language.

Although guideline recommendations should be evidence-based, some aspects of diabetes care will necessarily be based on clinical opinion, because some practices cannot ethically be tested by clinical trial (for example, the need for insulin in Type 1 diabetes) or have never attracted studies or trials. Best practice for recommendations in these areas is to use generally accepted clinical practice; however, some effort may be needed to determine this, and the recommendation developed may be regarded as weak.

Evidence statements and recommendations should be collated and circulated to the *Development Group* for review, and provision should be made for a further round of review if required.

Some points of detail are worth noting:

- It is not usual to provide stakeholders with evidence tables (the detailed assessment of each study identified and reviewed), although it is desirable if possible to publish them later in a full-length assessment report. The *Development Group* should also note evidence gaps in relation to the guideline questions.
- Where a series of statements are being made in different areas of care (for example, on review of eyes, feet, and educational skills, or targets for blood glucose, blood lipids and blood pressure), then there should be editorial attention to consistency of style from an early stage.
- For some areas, in particular patient education, the reach is so great that it has an impact on nearly all other aspects (consider insulin therapy, targets, monitoring, foot care, lifestyle issues, diet, cardiovascular prevention). In such areas, a recommendation statement may need to be earmarked for reconsideration when dealing with the other clinical questions.

### **2.2.7 Reconvene Steering Group for formal review and adoption of draft guideline**

As the draft guideline comes to completion the *Steering Group* should be reconvened to formally review and approve the developed draft guideline.

### 2.2.8 Circulate draft recommendations and evidence statements for comments

The draft evidence statements and recommendations should be circulated to stakeholders and interested individuals (see *Section 2.1*). A template for reply and a reasonable but strict deadline should be given. Printed and website material for open consultation should be clearly and repeatedly marked as 'Draft for consultation only — do not use or reproduce'.

A response should be prepared for each and every comment received, and should be kept as a record. Many comments will be useful and will result in changes, but only additional evidence-based material should be considered for inclusion. Disagreements, or strongly expressed opinions from major stakeholders, are best considered at a further meeting of the *Development Group*, to ensure that bias from governments and commercial organizations does not distort a fair view of the evidence.

### 2.2.9 Obtain endorsement

As soon as a near-final version is available, it should be circulated to the previously identified endorsing groups (see *Section 2.1.5*) for consideration for approval. Be prepared for this to take time. This procedure will facilitate implementation.

### 2.2.10 Design output document(s) and web pages, and publish

Design and content of output documents are important, and money spent on good formatting and high-quality printing will not be wasted. Web pages can nowadays consist of a pleasant and simple introductory page giving access to pdf files of the final guideline, as a whole and in sections.

The IDF recommends that the guideline should be published not only as a document for the use of healthcare professionals, but also in a form accessible to people with diabetes. This should not be a watered-down version of the guideline, but simply one that carefully avoids medical jargon. This is not easy — 'sulfonylurea' and 'blood lipids' are examples of terms that may not be easily understood.

In general, healthcare professionals and people with diabetes will not express great interest in the evidence assessment, any economic assessment, or even the evidence statements. These documents may, however, be important to local guideline developers when integrating the recommendations into local care protocols, and should thus be freely available. They should explicitly detail the most important considerations, including economic perspectives and potential for sustainable implementation. Many diabetes journals welcome systematic reviews, but international journals are only likely to take original reviews performed at the highest level.

Fortunately, websites offer large resources for making accessible all kinds of materials whose publication on paper would be inefficient and costly. A guideline website might contain:

- the complete set of recommendations (as published on paper)
- the recommendations by areas of care
- the recommendations in relation to the agreed evidence statements
- reference to any guideline methodology followed
- the methodology and sources used in the evidence review
- any evidence tables and economic analysis
- names and roles of the project team, *Development Group*, and *Steering Group*
- minutes of the *Development Group* and *Steering Group*
- declared duality of interest of members of the project team and *Development Group*
- names of stakeholders and others providing comment on the drafts
- details of funding.

## 2.3 Guideline development — practice points

### Guideline development checklist 3

#### Practice points

1. Naming the guideline
2. Language issues
3. Dating the guideline
4. Planning for updating
5. Development of performance review standards
6. Relation to other guidelines
7. Cost-impact concerns
8. Local variations in need
9. Disclaimer
10. Acknowledgements and duality of interest



### 2.3.1 Naming the guideline

Although the term ‘guideline’ has been used to describe the output document in this Guide, this word and related terms (‘standards’, ‘recommendations’, ‘advice’, ‘desktop guide’, ‘protocol’) may be interpreted quite differently even within the English-speaking world. Some interpretations of these terms are associated with perceived threats. This is an issue that needs to be addressed from the perspective of the parties involved in developing and implementing the document.

### 2.3.2 Language issues

While the language(s) of the guideline itself will have been defined at the planning stage, and provision made for any special expertise needed, there remains the potential problem that available *full-process guidelines* and evidence reviews are mostly in English. Evaluating the precise meaning of evidence statements and recommendations often demands good language skills. Specialist language skills may also be required in maintaining communication between interested parties during the guideline development process, and, as discussed above, in preparing a version of the guideline for people with diabetes.

### 2.3.3 Dating the guideline

The final version of the guideline needs to specify both the date at which the recommendations were made and the date of publication of the most recent evidence used in their development. It is also good practice to state the duration of validity of the guideline.

### 2.3.4 Planning for updating

There needs to be a statement of intention as to updating the guideline. If there is an umbrella organization to provide continuity, then it may be possible to specify a date, and plans should be made accordingly.

Within the guideline it may be helpful to caution over some recommendations if major new evidence is expected in the near future.

### 2.3.5 Development of performance review standards

Quality diabetes care includes activity devoted to ensuring the quality of delivered care, sometimes termed ‘audit’. Recommendations can be used to define a standard for performance review, such as the proportion of the target population who had feet examined in the last year, or the percentage of people seen with new foot ulceration. Setting these standards should be part of the normal guideline development process.

Such standards will also have a role later in evaluation of the impact of the developed guideline (see *Section 3.2*).

### 2.3.6 Relation to other guidelines

Diabetes care overlaps with many other areas of specialist healthcare. Geographically relevant guidelines may be available or may be being developed concurrently by groups interested in the management of blood pressure, blood lipids, obesity, pregnancy, children, the elderly infirm, and many others. Other groups may be working on structures of care, such as recall-review systems or healthcare delivery in primary care.

In addition, there may be national, regional or local initiatives on such things as healthy eating, or encouraging physical exercise.

It will aid implementation and acceptability if guidelines developed by different groups are in harmony, or the reasons for divergence made explicit. Liaison during development can extend ownership, and often the umbrella group of any other guideline can become a stakeholder.

### 2.3.7 Cost-impact concerns

Cost-effectiveness issues (discussed above) should be one of the major drivers of acceptability of the introduction of an advance in any area of care. However, healthcare budgets are limited and if the total funding needs of a change in healthcare are high, it may be difficult for healthcare managers to find the funding, however great the likely healthcare gain.

Nonetheless, new healthcare funding nearly always becomes available over time because healthcare budgets expand with increasing prosperity, while cost-improvements and reallocation of existing funds are often made in ongoing care delivery.

Your chances of overcoming the cost-impact barrier are much higher if:

- recommendations of high cost-impact are identified as early as possible
- the cost-effectiveness (cost-utility) case is well made (see Section 2.2.5)
- discussions of the issues take place with healthcare funders before publication of the guideline
- suggestions can be made for graded implementation over a limited number of years
- pilot implementation projects can be used to demonstrate the effectiveness and benefits of the intervention, and highlight variations of care between populations
- political advantage can be made out of an announcement of guideline implementation.

### 2.3.8 Local variations in need

In the absolute sense of an equitable standard of healthcare, guidelines should be insensitive to variations between populations. However, even within one geographical area, different populations will have different baseline levels of healthcare, so relative needs may differ. This is an issue for implementation, and of cost-impact. Need may also vary between groups in a population in ways which affect the equitable delivery of healthcare. For example, educational level and cultural differences may affect the optimal approaches to diabetes education. Cost-effectiveness of some processes may change within a population so that, for example, screening/surveillance for diabetes may be cost-effective in some groups and not in others.

Some of these issues will become obvious when considering special groups (see Section 2.1.7). Others (rural/urban, deprivation issues) may easily be missed if they are occurring within what might seem to be a relatively homogeneous population.

Qualitatively and quantitatively the goals and indicators of healthcare will not differ between people with diabetes living in developed and in developing countries. However, what is different is the availability of resources (human and economic), and this unfortunate fact conditions the need to use different approaches, methods and therapeutic strategies to achieve these goals.

*Qualitatively and quantitatively the goals and indicators of healthcare will not differ between people with diabetes living in developed and in developing countries. However, what is different is the availability of resources (human and economic), and this unfortunate fact conditions the need to use different approaches, methods and therapeutic strategies to achieve these goals.*

### **2.3.9 Disclaimer**

Your guideline should include a disclaimer to the effect that it is a general guideline only, that it may not apply in the case of any particular individual patient, and that it should be applied in the context of local health systems and using clinical expertise and judgement.

### **2.3.10 Acknowledgements and duality of interest**

In the interest of transparency, it is important that your guideline acknowledges all support received during the course of its development, and explains that collection, analysis and interpretation of the evidence and the decision to publish were independent of any interest groups including governments if appropriate.

Transparency about conflicts of interest is the key to credibility. If individuals involved in the process have areas of duality of interest these should also be made explicit, although while the nature of the interest should be given, the details need only be held by the project manager. Minutes of the *Development Group* and other meetings should similarly include such information.

# Implementing and Evaluating Guidelines

## 3

*A guideline is like a map showing where to go.  
Implementation is the journey and involves the real work of people with diabetes and providers.*

### 3.1 Guideline implementation

#### Guideline implementation checklist

##### Implementation

1. Review implementation strategy with responsible parties
2. Assist in establishing local implementation groups
3. Take account of local perspectives
4. Harness the energies of other interested parties
5. Arrange local launch meetings to disseminate ideas and endorse activities
6. Integrate into local professional education
7. Integrate into patient education activities



Effective guideline implementation strategies are essential for the adoption of the guideline recommendations and improving diabetes care. Many approaches have been used with varying success, but the most effective have been multidimensional and locally specific. The main targets of guideline implementation strategies are healthcare professionals, healthcare funders, and people with diabetes. However, other stakeholders (such as government and industry) have an important role in promoting and facilitating guideline implementation. The biggest challenge is to develop a locally relevant implementation strategy.

Planning for the implementation of a guideline is discussed above (see *Section 2.1.9*), and its importance as part of the preparation for a guideline is emphasized there. In *Section 2.1.2*, the action to be taken during guideline development to ensure that implementation issues are appropriately addressed is also discussed. The present section deals with issues arising after a guideline is complete and published. It is particularly aimed at the local implementation of a guideline developed at the national, regional or even international level.

#### 3.1.1 Review implementation strategy with responsible parties

The *Steering Group* should revisit the planned implementation process and confirm the stakeholders who will be pivotal in this process. The review should be done in conjunction with the group who initiated the guideline development (government, professional or patient organization), as they are likely to wish to have a major role in implementation.

##### Potential barriers to guideline implementation

1. Lack of a clear, feasible and practical implementation plan
2. Lack of endorsement by and involvement of key stakeholders
3. Lack of resources (personnel, materials and funding)



The identified representatives of stakeholders will often have changed, and the stakeholder group perspective on implementation issues may also have changed. It is quite likely that some aspects of healthcare policy will have changed in the time between planning a guideline and completing it. It is also likely that interest in the guideline will have broadened during the time spent in development and publication.

For all these reasons the guideline implementation strategy considered earlier in the planning process should be reviewed with interested parties as an early part of the implementation stage, and further buy-in and ownership sought.

### 3.1.2 Assist in establishing local implementation groups

Implementation of diabetes guidelines will always be a local issue. The *Steering Group* should oversee the identification of people or organizations who will take responsibility for assisting local stakeholders in establishing a local implementation group. This group will include people with diabetes, members of the multidisciplinary team, and people responsible for the management and financing of healthcare in the region or district, thus reflecting the structure of the *Steering Group*.

### 3.1.3 Take account of local perspectives

Local groups may require assistance in mapping the recommendations into local perspectives. Such assistance will also help to ensure that any local clinical practice recommendation will faithfully reflect the guideline recommendation, while the activity itself can be used to develop local ownership of the initiative.

Assistance can be made available for the preparation of local supporting materials, and for the rebadging of the original guideline outputs to reflect the interest and input from local groups, and to emphasize sources of local endorsement. Local groups may not be aware of the availability of programmed recall-review systems used in other localities, or of the design of patient-held records aimed at increasing the use of metabolic targeting in initiating and adjusting therapies. Other similar tools that are already available can be brought to their attention.

The *Steering Group* should be a reference point for local groups seeking information that might assist with implementation.

### 3.1.4 Harness the energies of other interested parties

The wider aspects of diabetes care overlap with many other areas of healthcare development, and local healthcare administrators may be able to point the way to potential areas of co-operation with groups such as those employed in reducing obesity, increasing physical activity, improving nutrition, reducing the prevalence of smoking, reducing cardiovascular risk, aiding ethnic minorities, or providing healthcare to those in residential and nursing homes.

Another source of skills is the pharmaceutical industry. Increasingly, some parts of industry are seeking to take a higher moral tone, recognizing that industry is a part of society and indeed a part of healthcare, rather than just a supplier to it. In any case, because diabetes care is both cost-effective and under-resourced, the effect of diabetes guidelines is usually to expand the diabetes market. Much of industry can make available considerable organizational and managerial skills; harnessing these without compromising impartiality is not usually difficult.

### 3.1.5 Arrange local launch meetings to disseminate ideas and endorse activities

Local launch meetings are an important means of publicizing guidelines, disseminating the philosophy and momentum of the guideline initiative, and bringing to a wider audience knowledge of the quality of the guideline, and its endorsement by others.

Local launch meetings should be mainly hosted and co-ordinated by respected local opinion leaders. External input should be limited to someone with detailed knowledge of the guideline and its development process; this individual should also be able to deal with anxieties that may surround perceived legal issues and concerns over restriction of care practice.

#### **Guideline implementation strategies**

1. **Guideline information:** leaflets, quick-reference guides for healthcare professionals and patients, websites
2. **Healthcare professional education:** workshops, academic detailing, lectures, conferences
3. **Patient education:** individual and group education, self-monitoring systems
4. **Reminders and recall systems:** including guideline-based computerized prompts, structured medical records, patient-specific reminders
5. **Audit and feedback**
6. **Incentives:** financial benefits, continuing professional education credits



### 3.1.6 Integrate into local professional education

Healthcare is often inherently conservative and difficult to change. Accordingly, even an active implementation process will quickly risk losing momentum and priority in local thinking.

However, in the longer term it is possible to influence future members of the healthcare professions through their educational curricula, and to secure wider knowledge of the existence and principles of a guideline by introducing it to those in training. This should be extended to continuing professional education, and to professionals in related specialties through postgraduate education.

A healthcare curriculum often reflects the knowledge and perspectives of those who choose to take an interest in medical education as a specialty, and often their own background remains linked to specific disease management as they learnt it. Integration of new thinking into the curriculum will therefore involve careful briefing of medical educators. For diabetes, opportunities can also be taken to achieve additional exposure through education modules addressing approaches to healthcare, such as multidisciplinary practice and patient empowerment, as well as evidence-based medicine itself.

### 3.1.7 Integrate into patient education activities

Equally important is integrating the guideline recommendations into patient education activities. People with diabetes should be specifically informed of the guideline content and encouraged to review their diabetes care to ensure it is in line with guideline recommendations. If the actual care they are receiving differs from the guideline recommendation, then they should be encouraged to discuss this with their medical practitioner and other healthcare providers. People with diabetes and their carers are a useful means of making healthcare professionals aware of new guideline recommendations.

## 3.2 Guideline evaluation

### Guideline evaluation checklist

#### Evaluation

1. Establish a monitoring system
2. Assess the effect on structures of care
3. Assess the effect on process of care
4. Assess the effect on diabetes outcomes
5. Assess the impact of the guideline itself



Evaluating guideline implementation is an integral part of completing the quality cycle to improve diabetes care through more effective and accessible care. Like implementation strategies, guideline evaluation must be considered throughout the guideline development process and should not be an afterthought.

It may be nearly impossible to assess the extent to which a guideline has changed practice, largely because positive changes in any field of healthcare often reflect multiple influences that are usually not independent. Is, for example, the expanding use of statins in Type 2 diabetes the result of a recently introduced local guideline, or the result of a recently published international guideline, or the result of the HPS and Steno-2 studies, or the lipid-lowering guidelines developed by the community cardiologist, or the activities of the pharmaceutical industry? A recommendation to implement patient education may tip the balance in appointing a further diabetes educator/nurse specialist, but is it the guideline recommendation that resulted in the appointment, or the groundwork done over the previous 18 months by the local diabetes advisory group?

This section considers evaluation of:

- care structures and resources
- process of care
- outcomes
- the guideline itself.

### 3.2.1 Establish a monitoring system

Guideline evaluation depends on the availability of an efficient monitoring system, including data collection and analysis. This may range from a paper-based system to a sophisticated computerized system, depending on local resources and available technologies. Information can be collected retrospectively from reviews of patient records, but it is better to have an ongoing, regular periodic review incorporated into routine clinical practice. Interviews with healthcare professionals and patients can also be used.

The monitoring system should include some capacity for feedback of the audit findings. This can take several forms. Computerized systems have the capacity to provide individual healthcare professional and patient feedback. Peer-review meetings are helpful for reviewing quality of diabetes care, and usually involve a member of staff presenting the audit results to other members of the clinical team.

### 3.2.2 Assess the effect on structures of care

Guidelines may recommend the establishment of particular care structures (for example, diabetes centres) or the use of particular kinds of equipment (digital eye cameras or photocoagulation lasers). The provision of these is particularly easy to monitor, although it is of importance to demonstrate that care resources are being used appropriately (see *Section 3.2.3*) and effectively (see *Section 3.2.4*).

### 3.2.3 Assess the effect on process of care

Guideline recommendations invariably include explicit details about process of care. Whether or not these recommended processes of care are being implemented can readily be evaluated.

Process of care can be considered in the following categories (with examples):

- Attendance at health professionals — annual review, educator, nutritionist
- Frequency of examinations — blood pressure, feet, eyes
- Frequency of tests — blood glucose control, lipids, urine
- Achieving targets — blood pressure, blood glucose control measures, lipids
- Self-care management — self-monitoring, diet, physical activity.

At a patient level the desired outcome is that all people should receive the recommended processes of care. However, in reality there may be a number of reasons why this cannot be achieved in some individuals. At a practice, clinic or local level it is possible to set realistic targets for the percentage of people who should receive recognized standards of care (such as 80% of people having blood pressure checked, or 70% of people having an eye check). These targets should be set locally using the standards developed with the guideline (see *Section 2.3.5*), should take into account baseline levels of care, and should aim to steadily improve on these. The targets should not be static but should increase over time as progress is made against guideline implementation.

Monitoring of diabetes care is not simply designed to identify categorical success or failure. Rather, it should highlight sectors of care where changes are needed which might be addressed by increasing or redeploying resources, or by improving equity of access.

### 3.2.4 Assess the effect on diabetes outcomes

The ultimate goal of improved diabetes care is to reduce the impact of diabetes on both the individual and society. This is reflected in improved diabetes outcomes, and can be assessed in terms of diabetes-specific outcomes and improved quality of life.

#### *Diabetes-specific outcomes*

Which outcome measures should be assessed will depend on the scope and breadth of the guideline, but might include some or all of the following:

- Prevalence and incidence of diabetes
- Intermediate outcomes: glucose and blood pressure control
- Markers of adverse outcomes: retinopathy, decreased sensation, markers of kidney damage
- Adverse patient outcomes: visual loss, foot ulcers, amputation, myocardial infarction, stroke, dialysis, transplantation, death
- Hospitalization.

For late complications of diabetes, diabetes-related death and hospitalizations, realistic time-dependent targets should be set to reduce the number of people affected by the diabetes-specific outcome which is the focus of the guideline. For other outcomes (such as prevalence), a reduction in projected increase, rather than an overall reduction, may be a more realistic target. The monitoring system is essential for assessing the impact of guidelines on patient outcomes.

#### *Quality of life*

People with diabetes, especially those with complications, have a reduced quality of life compared with age-matched non-diabetic individuals. Change in quality of life is a useful outcome measure. There are a number of simple validated measures of quality of life, including the WHO-5 Well-Being Scale and the EuroQol EQ-5D. An evaluation of quality of life is also necessary for cost-utility analyses (see below and *Section 2.2.5*).

#### **3.2.5 Assess the impact of the guideline itself**

The guideline itself should also be evaluated to ensure that it is accepted by healthcare professionals and people with diabetes, that its implementation is feasible within the clinical setting, and that patients and healthcare professionals are satisfied with the guideline recommendations. In addition, the prospective collection of costing data in relation to diabetes health outcomes and quality of life allows a detailed economic evaluation of guideline recommendations. Consideration of these and related issues is essential when the guideline is being updated.



## Source Websites

<a href="http://www.agreecollaboration.org">www.agreecollaboration.org</a>	Tool for assessing quality of guidelines
<a href="http://www.deutsche-diabetes-gesellschaft.de">www.deutsche-diabetes-gesellschaft.de</a>	<i>Full-process guideline</i> (Leitlinien)
<a href="http://www.diabetes.ca">www.diabetes.ca</a>	<i>Full-process guideline</i> (with French links)
<a href="http://www.guideline.gov">www.guideline.gov</a>	Tool for assessing quality of guidelines
<a href="http://www.icsi.org">www.icsi.org</a>	<i>Full-process guideline</i>
<a href="http://www.idf.org">www.idf.org</a>	This document (pdf), IDF activities
<a href="http://www.nhmrc.gov.au">www.nhmrc.gov.au</a>	<i>Full-process guideline</i> , methodology
<a href="http://www.nice.org.uk">www.nice.org.uk</a>	<i>Full-process guideline</i> , methodology, economics
<a href="http://www.nzgg.org.nz">www.nzgg.org.nz</a>	<i>Derived guideline</i> , methodology
<a href="http://www.sign.ac.uk">www.sign.ac.uk</a>	<i>Full-process guideline</i> , methodology



# Glossary

## Terms used in this Guide

*(Economic jargon is explained in the box in Section 2.2.5)*

**Derived guideline** is the term used in this Guide for a guideline which develops clinical questions, but then seeks out and adapts previously developed *full-process guidelines*, updating the evidence base and seeking supporting evidence to develop recommendations for local circumstances.

**Development Group** is the term used in this Guide to describe the group which has the responsibility for considering the evidence identified by systematic review, and for formulating the clinical recommendations.

**Full-process guideline** is the term used in this Guide for a guideline which involves a full and systematic development of the clinical questions to be addressed, and develops recommendations supported by complete and formal evidence searching and review, using primary sources.

**Remit** is the area to be covered by the guideline, as outlined by the initiators of the project.

**Scope** is the detail within the area covered by the guideline, as determined during the scoping process.

**Stakeholder** is a person who has a stake or interest in the process or its outcome.

**Steering Group** is the term used in this Guide to describe the group which, meeting infrequently, ensures that representatives of all stakeholder organizations can be heard. It provides the means of reviewing management performance and the draft recommendations, and ultimately will sign-off the guideline, giving it broad legitimacy.



# Acronyms

ACE	angiotensin converting enzyme
AIDS	acquired immunodeficiency syndrome
DCCT	Diabetes Control and Complications Trial
GDP	gross domestic product
HPS	Heart Protection Study
QALY	quality-adjusted life year
RCT	randomized controlled trial
SIGN	Scottish Intercollegiate Guidelines Network
UKPDS	United Kingdom Prospective Diabetes Study
WHO	World Health Organization



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